

### REMARKS

Applicants respectfully request consideration of the subject application. This Response is submitted in response to the Office Action mailed November 1, 2007. Claims 1-14 are pending. Claims 1-14 are rejected. In this Amendment, claims 1 and 4 have been amended and claim 15 has been added. No new matter has been added.

#### 35 U.S.C. § 112 Rejections

The Examiner has rejected claim 4 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants have amended claim 4. Applicants, accordingly, respectfully request withdrawal of the rejections under 35 U.S.C. § 112.

#### 35 U.S.C. §§ 102 and 103 Rejections

The Examiner has rejected claims 1-3, 5-7 and 9-11 under 35 U.S.C. § 102(b) as being anticipated by Stoyan, (U.S Patent No. 6,010,219, hereinafter "Stoyan"), claims 12-14 under 35 U.S.C. § 102(a,e) as being anticipated by Mitsui (U.S Patent Publication No. 2003/0095232, hereinafter "Mitsui"). The Examiner has rejected claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Stoyan

as applied to claim 1 and further in view of Volk (U.S. Patent No. 3,482,906, hereinafter "Volk").

Applicants do not admit Mitsui is prior art and reserve the right to swear behind Mitsui at a later time.

Stoyan fails to describe a soft orthokeratology lens and provides no describe as to how to design or manufacture a soft lens that has an orthokeratology effect.

Stoyan describes a wide range of lens diameters and range of different lens materials, from soft to hard. At col. 3, line 14, in particular, Stoyan describes a lens diameter between 5 and 20mm. At col. 4, line 61, Stoyan explains that the lens can be made from hard or soft materials; however, Stoyan requires that the central portion of the lens be hard, since it is that portion which is required to apply pressure to the center of the cornea in order to achieve an orthokeratology effects.

The range of lens diameters described in Stoyan spans two general types of contacts lenses. The first type, corneal contact lenses, have diameters below the limbus/corneal diameter (around 11 to 12mm). These are necessarily made of a rigid material to ensure lens centration with the cornea. The other lens type has diameters above this limbal diameter. It is well known that at the limbus (the junction between the cornea and sclera), there is a change in curvature/surface

profile of the eye. Hence, larger diameter lenses must be designed to address this shape discontinuity, and functional lenses are typically made of soft materials to accommodate this surface profile change at the limbus without causing severe discomfort.

Stoyan does not describe the limbus or sclera anywhere in the specification. Thus, Stoyan is dealing only with the smaller than limbal diameter corneal contact lenses. It is well known to those of skill in the art that the materials and designs of the two lens types are very different and that the diameters for the two types of lenses are very different. Thus, Stoyan merely describes rigid lenses, and, therefore, does not relate to the problems of designing a soft lens that can have an orthokeratology effect.

Stoyan provides two specific examples. At col. 3, line 17, Stoyan mentions that the lens diameter is in the neighborhood of 10mm; that is, the lens diameter is smaller than the limbal diameter. At col. 5, line 53, Stoyan describes another example in which the lens diameter is 9.6mm (also smaller than the limbal diameter).

The diameter, in contrast, in the presently pending claims, is greater than the limbal diameter. Furthermore, the lens is formed of a homogenous soft material with an elastic modulus of between 0.2 and 10MPa, which is also not taught or suggested by the cited art.

Similar to Stoyan, Mitsui does not contemplate the use of soft contact lenses in the procedures described therein. The discussion of the types of lenses that would work in the Mitsui process is set forth in paragraph [0073] of Mitsui. Specifically, Mitsui describes the use of Paragon Fluroperm 60 and 90 lenses, which are rigid gas permeable lenses. Exhibit 1, attached hereto, provides a future discussion of these lenses. Thus, Mitsui does not contemplate the use of soft lenses.

Applicants submit herewith an article (Exhibit 2) by Helen Swarbrick, a world expert in orthokeratology from the journal "Clinical and Experimental Optometry," May 2006, which defines orthokeratology as a "clinical technique that uses specially designed and fitted rigid contact lenses to reshape the corneal contour to temporarily modify or eliminate refractive error." Thus, even as recently as 2006, it was assumed by those of skill in the art that only hard lenses would be suitable for orthokeratology techniques. Thus, one of skill in the art would not modify the cited art to arrive at the presently pending claims.

It is well known that orthokeratology requires the central region of the eye to be flattened by fitting a lens shaped to apply pressure to that central region. Accepted wisdom was that the necessary pressure could only be achieved using rigid (i.e., hard) lenses. Neither Mitsui nor Stoyan suggest that a soft lens might be capable of applying the necessary pressure.

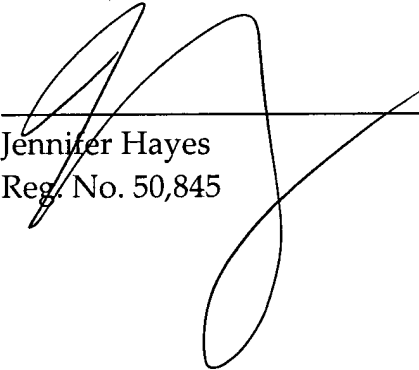
Thus, the cited art fails to teach or suggest all of the limitations of independent claims 1 and 12. Claims 2-5, 7-11 and 13-14 depend, directly or indirectly, from one of the foregoing independent claims. Applicants, accordingly, respectfully request withdrawal of the rejections under 35 U.S.C. § 102 and § 103.

Applicants respectfully submit that the present application is in condition for allowance. If the Examiner believes a telephone conference would expedite or assist in the allowance of the present application, the Examiner is invited to call Jennifer Hayes at (408) 720-8300.

Please charge any shortages and credit any overages to Deposit Account No. 02-2666. Any necessary extension of time for response not already requested is hereby requested. Please charge any corresponding fee to Deposit Account No. 02-2666.

Respectfully submitted,  
Blakely, Sokoloff, Taylor & Zafman LLP

Date: 3-31-00

  
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